VIZIENT OFFICE OF PUBLIC POLICY AND GOVERNMENT RELATIONS

Notice Regarding 340B Rebate Model Pilot Program

August 5, 2026

SUMMARY

On July 31, the Health Resources and Services Administration (HRSA) issued a notice regarding the availability of a revised 340B Rebate Model Pilot Program (Pilot) (hereinafter, "Notice"). The Pilot provides a rebate mechanism, rather than an upfront discount, through which qualifying drug manufacturers may effectuate the 340B ceiling price for certain drugs sold to covered entities (CEs). Manufacturer participation is voluntary, but an approved manufacturer plan would directly impact CEs acquiring affected 340B drugs, as 340B pricing would be available by a rebate, among other changes. CEs will order affected products through existing distribution channels with wholesale acquisition cost (WAC) prices loaded and submit specified claim-level data to obtain unit-level rebates. The Pilot applies regardless of payer or indication.

The Notice is effective upon publication, unless revised by a future notice. HRSA reserves the right to issue revisions or addenda at a later date. Eligible manufacturers must submit plans to HRSA by August 24, 2026, for a January 1, 2027, effective date covering selected drugs for initial price applicability years (IPAYs) 2026 and 2027 during their price applicability periods.[1]

BACKGROUND

Section 340B of the Public Health Service Act (PHSA) requires pharmaceutical manufacturers participating in Medicare Part B (which covers physician-administered drugs) and Medicaid to sell drugs at reduced prices to covered entities.[2] The Department of Health and Human Services (HHS) enters into pharmaceutical pricing agreements (PPAs) with manufacturers of covered outpatient drugs, as required by law. When a drug manufacturer signs a PPA, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. 340B ceiling prices are based on quarterly pricing reports that manufacturers provide to the Centers for Medicare & Medicaid Services (CMS) and are calculated by HRSA.

REBATE MODEL PILOT PROGRAM

SCOPE OF PRODUCTS

The Pilot applies only to the National Drug Code (NDC) of selected drugs for IPAYs 2026 and 2027 included on the CMS Medicare Drug Price Negotiation Selected Drug List, regardless of payer or indication, and only during each selected drug's price applicability period.

MANUFACTURER PARTICIPATION

HRSA invites qualifying drug manufacturers that meet the eligibility criteria to apply for participation in the Pilot for at least one year. Manufacturer plans for participation in the Pilot must be submitted to 340BPricing@hrsa.gov no later than August 24, 2026. Approvals, if any, will be made by September 24, 2026, for a January 1, 2027, effective date for approved IPAYs 2026 and 2027 selected drugs. Manufacturers may not implement a plan without prior HHS approval.

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[1] IPAY 2026 and 2027 refer to the first two Initial Price Applicability Years for the Centers for Medicare and Medicaid Services (CMS) Medicare Drug Price Negotiation Program. For IPAYs 2026 and 2027, CMS negotiated the Maximum Fair Prices for high-spend Part D drugs. IPAY 2026 began January 1, 2026 and IPAY 2027 will begin January 1, 2027.

[2] To prevent duplicate discounts, the law provides that covered entities shall not request a discount for a drug that is already subject to a separate Medicaid rebate requirement.

MANUFACTURER PLANS

Manufacturer plans must meet the criteria provided in Table 1. A plan that includes content outside of these criteria must include detailed justification and will receive additional HRSA review. HRSA will notify each manufacturer whether its plan is approved. HHS may revoke approval at any time if the manufacturer does not comply with these criteria or other requirements in its approved plan. As outlined in Table 1, manufacturers will need to select an IT platform which will be utilized for various functions, including data submission with CEs, technical assistance, and the provision of real-time reconciliation reports. CEs should be aware of key timelines, including the 45-calendar-day window to submit required data from the date of dispense and that manufacturers must give CEs at least 90 calendar days of notice before implementing an approved plan.

Table 1. Content that manufacturer plans must meet for HRSA approval.

Topic	Additional Information
General 340B Rebate Model Pilot Plan Requirements	The plan must identify the IT platform for covered entity data submission and confirm that the manufacturer will bear all platform costs.
	Manufacturers must give covered entities and other affected stakeholders at least 90-calendar-days notice before implementing an approved plan, including instructions for registering on any IT platform. The Office of Pharmacy Affairs (OPA) must approve plan changes before implementation and will decide whether another covered entity notice period is required. Manufacturers are expected to provide HRSA with the final approved plan for public posting.
	Covered entities must be able to order selected drugs through existing distribution channels, such as 340B wholesaler accounts with WAC prices loaded.
	Manufacturers must provide technical assistance and customer service through the IT platform and a manufacturer point of contact, including opportunities for covered entities to engage directly and in good faith about questions or concerns.
	The IT platform must secure and protect submitted data and limit collection to the elements listed below that are necessary to provide 340B rebates.
	The manufacturer and platform must safeguard protected health information (PHI) and other personally identifiable information (PII) consistent with applicable federal privacy and data-security laws, including the Health Insurance Portability and Accountability Act.
	Plans must identify any exceptions that would not apply to all covered entities and explain how the manufacturer will communicate them to HRSA and affected covered entities, including entities without access to a third-party administrator and rural hospitals or health centers.
Reporting Requirements	Covered entities must have at least 45 calendar days from the date of dispense to submit required data. Plans must allow for extenuating circumstances, other exceptions, and corrections when a claim's 340B status changes.
	The platform must accept data from applicable CEs and filter information not needed to provide rebates.
	Manufacturers must ensure that the IT platform will have the capability to provide real-time reconciliation reports for covered entities to be informed of the rebate status of submitted claims.
	Manufacturers must ensure that a quarterly 340B price file for each of the manufacturer's 11-digit NDCs is made available to covered entities, so that covered entities may use the price file in conjunction with pharmacy billing systems to appropriately account for actual acquisition cost (i.e., post rebate price) for Medicaid billing and also to assist with sliding fee scales or cost sharing with patients.
	Manufacturers must submit periodic reports to HRSA/OPA in a forthcoming format specified by HRSA/OPA. Such data should detail data on purchases provided through rebates, information related to claim denials, and other information that may evaluate the effectiveness of the rebate model.
Rebates	Plan must include the rebate calculation equal to the wholesale acquisition cost (WAC) less the 340B ceiling price on the day of dispense.
	Rebates must be paid at the unit level.
	Plan must include details to accommodate up to two unreplenished accumulated packages during the implementation phase. Covered entities shall have a 15-calendar day grace period, in which they may submit rebate requests for up to two unreplenished accumulated packages prior to the Pilot's effective date. For example, a covered entity may request a rebate for up to two packages of a product dispensed

	from its neutral inventory on December 16, even though the effective date for the product's participation in the pilot is January 1. The request for such rebates should still be made within 45 days of dispense.
	Manufacturers must pay the rebate (or deny it with supporting documentation) within 10 calendar days after a complete data submission. If a submission is incomplete, the 10-day period restarts when all necessary data are submitted.
	Plan must ensure that 340B rebates are not denied based on eligibility or compliance concerns with diversion or Medicaid duplicate discounts and should provide for rationale and specific documentation for reasons claims are denied (e.g., nonduplication of discounts for a selected drug for which the MFP is required under the MDPNP or 340B rebate provided to another covered entity on the same claim). Rebates may not be denied for perceived lack of WAC purchases. If a manufacturer has concerns regarding Medicaid duplicate discounts, diversion, eligibility, or insufficient WAC purchases to support rebate requests, the manufacturer must raise those concerns directly with HRSA/OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution, for addressing such issues. Covered entities can also raise concerns with HRSA/OPA if there are issues with rebate denials through reporting tools sent to 340Bpricing@hrsa.gov.
	Plans may apply the rebate model only to the NDCs of active IPAY 2026 or 2027 selected drugs on CMS's Medicare Drug Price Negotiation Selected Drug List, regardless of payer or indication, and only during each selected drug's price applicability period.
Data[3]	All data requested as part of the Plan should be limited to only the following claim fields[4]: - **Pharmacy Claims Data Fields**[5]**:** Date of Service, Date Prescribed, Rx Number, Fill number, NDC-11, Quantity dispensed, Prescriber ID, Service Provider ID, 340B ID, RX BIN, RX PCN - **Medical Claims Data Fields**: Date of Service, Claim line number, Claim number, Unit of Measure, NDC-11, Quantity, Rendering Physician ID, Service Provider ID, 340B ID, Health Plan Name, Health Plan ID, Health Plan ID Qualifier (if available)
	Covered entities must be allowed to resubmit requests that are incomplete or missing data.
	Manufacturer plans must include, and manufacturers must communicate, instructions for reporting wasted or undispensed units.

SCALE AND ESTIMATED BURDEN

Using 2025 data, HRSA estimates that included products represent less than 5.5% of total 340B sales and that the remaining 94.5% of drug sales will continue under the upfront-discount model in 2027. HRSA estimates annual claims-reporting costs of approximately $523.3 million across 15,249 covered entities, averaging approximately $34,320 per entity, with costs varying by entity type.

PILOT EVALUATION AND TRANSPARENCY

HRSA will evaluate the Pilot using a combination of quantitative and qualitative methods. Quantitative measures will include data submitted by participating manufacturers and CEs regarding rebate requests, rebate payments, payment timeliness, claim denials, dispute resolution outcomes, reporting burden, and other operational metrics. HRSA will also review information relating to administrative burden, duplicate discount prevention, data quality, and program integrity and may use data gleaned from the Pilot during reviews of routine 340B Program audits of both covered entities and manufacturers. HRSA will publish interim periodic summaries of implementation findings. Upon conclusion of the first year of Pilot operations, HRSA will publish an evaluation by April 30, 2028.

[3] CE data that is handled by technology platforms and received by manufacturers as a part of the Pilot should not be used for purposes other than those explicitly identified in the Notice (this extends to any collecting, aggregating, sharing, or licensing of Pilot data by manufacturers or technology platforms).
[4] Data definitions for each field must be submitted with the plan for HRSA's approval to ensure consistency and make it available for covered entities. Purchasing data and encounter data requests should not be requested as part of the pilot at this time
[5] For BIN, PCN, and Health Plan fields for uninsured or cash paying patients, manufacturers should allow the submission in the fields to be marked "CASH".

WHAT'S NEXT?

There is no comment period for the Notice. The Notice is effective immediately as published, unless revised by a future notice. Approved manufacturer plans may take effect January 1, 2027.

We encourage you to reach out to our office if you have any questions or comments regarding the Notice, including provisions that cause concern. Please direct your feedback to Jenna Stern, Vice President, Regulatory Affairs and Public Policy in Vizient's Washington, D.C. office.

TO LEARN MORE, CONTACT:
Vizient's Office of Public Policy & Government Relations at (202) 354-2600 or VizientGR@vizientinc.com